SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND C2 lyophilisate for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Live attenuated Newcastle disease virus (NDV) strain C2: 5.7 - 7.5 $\log_{10}$ EID_{50}* per dose.

*EID_{50} = 50% Embryo infective dose: the virus titre required to produce infection in 50% of the embryos inoculated

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension.

Vials: white/off-white coloured pellet.
Cups: white/off-white, predominantly sphere shaped.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

Active immunisation of chickens against Newcastle disease virus to reduce clinical signs and mortality.

Onset of immunity: 2 weeks after vaccination of seronegative animals.
Duration of immunity: 5 weeks after vaccination of seronegative animals.

Onset of protection is demonstrated at 2 weeks after vaccination of animals with maternally derived antibodies.

Duration of immunity is in accordance with the vaccination programme.

4.3 Contraindications

Do not vaccinate clinically ill (especially respiratory disease) or stressed birds.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
The vaccine virus may spread to unvaccinated birds up to 10 days post vaccination. This spread does not induce clinical signs but may lead to seroconversion in unvaccinated chickens.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Live Newcastle disease vaccines may cause a mild transient conjunctivitis in the person administering the vaccine. Appropriate measures should be taken to prevent this.
Wash and disinfect hands and equipment after vaccinating. When used by spray, contact of eyes and airways with the vaccine virus should be prevented. Personal protective equipment consisting of a face mask should be worn when spraying the vaccine.

4.6 Adverse reactions (frequency and seriousness)

Blinking or headshaking may be observed when ice-cold vaccine is administered via the eye/nose drop method.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay or within 4 weeks before the start of the laying period (as the safety of this has not been investigated).

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered to 1-day old chicks on the same day, but not mixed, with Innovax-ILT, or the Nobilis live vaccines against rhinotracheitis (strain 11/94). Marek's disease (strains CVI988-FC126) or infectious bronchitis (strain IB Ma5) are compatible with Nobilis ND C2 when non mixed and given on day 1. The efficacy of the Marek and IB Ma5 vaccines has not been investigated.
Safety and efficacy data are available which demonstrate that the Nobilis live vaccine against Infectious bursal disease vaccine (strain D78) can be given 7 days after Nobilis ND C2.
Safety and efficacy data are available which demonstrate that Nobilis ND C2 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-IBD.
Safety and efficacy data are available which demonstrate that Nobilis ND C2 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-ILT.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Administration via oculonasal use or via (coarse) spray.
Single vaccination with one dose per animal from 1 day of age onwards.

The vaccine may be delivered as a freeze-dried cake in a glass vial or as freeze-dried spheres in cups. In case of the product presented in cups, do not use the product if the contents are brownish and stick to the container as this indicates that the integrity of the container has been breached. Each container should be used immediately and completely after opening.

Oculonasal administration
Reconstitute the vaccine with the appropriate amount of a suitable diluent and administer by means of a standardised dropper (of which the droplet size is known and consistent). Sterile distilled water or phosphate buffered saline can be used. The amount of diluent required for eye- or nose-drop administration depends on the number of doses and the droplet size, but approximately 35 ml per 1000 doses is used. One drop should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

Spray
Reconstitute the vaccine in cool, clean water, to which 2% skimmed milk may be added. The vials should be opened under water or the content of the cup(s) should be poured into water. Chlorinated water should not be used. In both cases mix the water containing vaccine well before use. After reconstitution the suspension looks clear. The water and spray apparatus should be free from sediments, corrosion and traces of disinfectants or antiseptics. Ideally the apparatus should be used for vaccination purposes only. The volume of diluent for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds. This will vary according to the age of the birds being vaccinated and the management system, but 250 to 500 ml of water per 1000 doses is suggested. The vaccine suspension should be sprayed evenly over the birds at a distance of 30-40 cm, preferably when the birds are sitting together in dim light. If applicable, reduce or stop ventilation to prevent loss of spray.

Vaccination programme
Nobilis ND C2 can be given from 1 day of age onwards. Because the immunity which is induced by vaccination with Nobilis ND C2 is not long lasting, an extended vaccination programme should be followed. To maintain a required level of immunity, chickens should receive a secondary vaccination 2-3 weeks after administration of this vaccine, with a live vaccine containing the more immunogenic Clone 30 strain.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No other signs than after a single dose are seen after administration of ten times the maximum dose via the recommended routes.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live Newcastle disease virus vaccine.
ATCvet-code: QI01AD06

To stimulate immunity against Newcastle disease in chickens.
The attenuated C2 strain is lentogenic and of low pathogenicity and is therefore suitable from 1 day of age.
Priming effect of ND C2 has been demonstrated exclusively by secondary vaccination of chickens with the live NDV vaccine containing the more immunogenic Clone 30 strain.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Hydrolysed gelatine
Pancreatic digest of casein
Disodium phosphate dihydrate
Purified water

6.2 Major incompatibilities

Do not use with any other veterinary medicinal product, except the products mentioned in section 4.8.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after reconstitution according to directions: 3 hours.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Protect from light.

Store below 25°C after reconstitution.

6.5 Nature and composition of immediate packaging

Cardboard box containing 1 or 10 vials of glass (hydrolytic glass type I or glass type II) with halogenobutyl rubber stopper and metal cap.
Contents per vial: 500, 1000, 2500, 5000, 10 000 or 25 000 doses.

Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer.

Pack sizes:
Cardboard box with 1 or 10 vials of 500 doses.
Cardboard box with 1 or 10 vials of 1000 doses.
Cardboard box with 1 or 10 vials of 2500 doses.
Cardboard box with 1 or 10 vials of 5000 doses.
Cardboard box with 1 or 10 vials of 10000 doses.
Cardboard box with 1 or 10 vials of 25000 doses.
PET plastic boxes with 12 cups of 1000 doses
PET plastic boxes with 12 cups of 2500 doses
PET plastic boxes with 12 cups of 5000 doses
PET plastic boxes with 12 cups of 10 000 doses

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4626

9. DATE OF FIRST AUTHORISATION

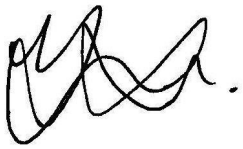
25 April 2005

10. DATE OF REVISION OF THE TEXT

December 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.



Approved: 14 December 2022